



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,271	04/14/2004	Shibnath Ghosal	4822-111.1 US	6209
<div>7590 03/28/2007 Diane Dunn McKay, Esq. Mathews, Collins, Shepherd &amp; McKay, P.A. Suite 306 100 Thanet Circle Princeton, NJ 08540</div>			<div>EXAMINER HEARD, THOMAS SWEENEY</div> <div>ART UNIT 1654 PAPER NUMBER</div>	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/824,271	GHOSAL, SHIBNATH	
	<b>Examiner</b>	<b>Art Unit</b>	
	Thomas S. Heard	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 9, 10, 13, 14, 17, 26, 29, 39 and 40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1, 9, 10, 13, 14, 17, 26, 29, 39, and 40 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/16/2007 has been entered.

The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 1/5/2007 are hereby withdrawn.

Claims 1, 9, 10, 13, 14, 17, 26, 29, and the new claims of 39, and 40 are pending. The Applicant has canceled claims 2-8, 11, 12, 15, 16, 18-25, 27, 28, and 30-38.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9, 10, 13, 14, 17, 26, 29, and the new claim 39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such

Art Unit: 1654

a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, no that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Art Unit: 1654

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In *re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

Applicant's arguments have been carefully considered but are not found persuasive.

Applicants have argued

The claims recite specific structural elements of the composition rather than reciting elements by mere statements of function. The specification states that the identities of the colored compounds (carotenoids) were established by HPLC using authentic markers. (Page 4, lines 18-29). Thus, the limitation directed to the identity of the chromopeptides was proven in the laboratory and rebuts the examiner's argument that there is not a specific example that discloses a DBP with specific chromoproteins. Amended claim 1 specifies these chromopeptides.

The Examiner stated that "there is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety." There is a specific example. The formula shown on pages 5 and 6 of the specification provides a clear depiction to support a claim for a composition of isolated dibenzo-alpha-pyrone chromoproteins as claimed in independent claim 1 and 26. The formula provides the structure of the dibenzo-alpha-pyrone moiety and provides for alternative choices of substituents. Furthermore the formula provides for various species of lipids having fatty acyl esters of glycerol. Disclosure of specific chromoproteins is found in the reduction to practice description of Example 4 (page 22), wherein two chromoproteins are described by a combination of identifying characteristics.

The Examiner stated that "the presumed structure example does not share a common core structure, as creatine (and other functional moieties) can be presumably

Art Unit: 1654

connected to R3 or R8 without any evidence." Here, the fact that the claim provides for creatine at the R3 or R8 positions is not a lack of written description, since these two structures are described in the specification, e.g., at page 2, line 20, et seq. Second, it is not the case that these structures were provided without any evidence. The specification describes that saponification of the larger molecule provided smaller molecules which were identified and interpretation of the data led to the determination of the structure of the larger DCP. The specification describes that saponification resulted in the occurrence of creatine (page 5, line 7 et seq.).

The Examiner stated "the claimed and disclosed molecular structure is merely a potential structure based on chemical and not structural determination." First, patentability of product cannot be denied on the basis of the method of making it. It doesn't matter whether the claimed molecular structure was conceived as a result of chemical or structural analysis. Furthermore, the claimed and disclosed molecular structure is not a "potential structure," it is definite. It is presented as a structural formula with definite options for the constituents. So long as one skilled in the art would understand what that structure is, the written description requirement is satisfied.

It appears, from these remarks that the Examiner's basis for the rejection is based on the drafter's choice of the term "suggested." Applicant argues that this is a case of rejecting form over substance. The inventor determined the claimed structure based on experimental procedures and has provided evidence of the results in figures 2, 3, and 4 and in the examples. B-48 is not a claimed substituent, so criticism of the description of B-48 does not constitute proper grounds for the rejection. Low/medium weight lipoproteins are not a claimed constituent. What is claimed as a constituent is fatty acyl esters of glycerol, of carbon chain length about C 14 to about C24. This is supported by description of the lipase degradation reaction that liberated phospholipids containing C~4-C24 fatty acids (page 4, line 30 et seq.).

The Examiner has considered the methods by which the "structures" were determined and respectfully disagrees with the conclusion. The use of the word "suggested" clearly implies that a specific protein has not been identified. It appears that the structures drawn in the specification were speculative. The Applicants are attempting to describe what appears to be literally thousands of different compounds by, at best, a qualitative methodology. How does the Applicant know that R<sup>5</sup>, R<sup>6</sup>-R<sup>10</sup> have OH, O-acyl, O-amino-

Art Unit: 1654

acyl, and fatty acyl groups? Just because they were liberated in a given reaction does not mean they were liberated from those positions. How do the Applicants independently select from those groups all of the individual compounds that they are proposing when the isolate is a mixture of thousands of potential different structures? Why is creatine assigned to C(3)? Why not at another hydroxyl position? In the reference of Ghosal, S, "Shiljit: Its Origin and Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319., there is no teaching, on page 311, that there are other position that can be labeled with acyl-groups, or hydroxyl groups. Further, the chromo-peptides comprising a carotenoid moiety, said carotenoid moiety is astaxanthin and equivalents also lacks written description.

The Applicants have drawn a structure but have not performed any structural studies to conclusively show that the structure drawn is what they have determined by the saponification and other qualitative chemical reactions. It is for this reason that the Examiner has made and maintains a Written Description rejection, because a drawing for a proposed structure does not mean the Applicants are in possession of that structure, absent structural studies.

Thus, as stated previously the factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to shilajit extract containing oxygenated dibenzo-alpha-pyrone chromoproteins compounds.

*(1) Level of skill and knowledge in the art:*

The level of skill to practice the art of the instantly claimed invention is high with regard to isolation, fractionation, and characterization, particularly with respect to mass spectroscopy, nuclear magnetic spectroscopy, and other spectroscopic methods of determining the structure of a complex molecule.

*(2) Partial structure: (3) Physical and/or chemical properties:*

Dibenzo-alpha-pyrones conjugated covalently to other alleged elements, such as lipids, amino acids (peptide), chromo-peptides, phosphocreatin, caretenoids, and various metals.

*(4) Functional characteristics:*

Thought to have medicinal value from traditional systems, see Ghosal, S, "Shiljit: Its Origin and Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319.

*(5) Method of making the claimed invention:*

Hot aqueous extracts assisted with organic solvent.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is



unquestionable that claim 1-12 and 26-29 are a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any structure class comprising dibenzo-alpha-pyrone. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety. The presumed structure example does not share a common core structure, as creatine (and the other functional moieties) can be presumably connected to R<sup>3</sup> or R<sup>8</sup> without any evidence. While having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules. The claimed and disclose molecular structure is merely a potential structure based on chemical and not structural determination. Lipase reactions "suggested" that lower MW lipids were present and that higher MW proteins, "like B-48" might be present in dibenzo-alpha-pyrone, see pages 23 and 24 of the specification.

Art Unit: 1654

The "suggestion" that "dibenzo-alpha-pyrone are associated with low/medium weight lipoproteins is also indicative of the molecule not being completely described as to have proper written description. Thus, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1, 9, 10, 13, 14, 17, 26, 29, and the new claim 39 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition of a fractionated extract of Shilajit, does not reasonably provide enablement for the specific compositions instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have argued:

The Examiner stated that "the specification has provided an alleged structure, or best guess of a generic ... Applicant has pointed out that all claimed limitations are

Art Unit: 1654

supported by scientific evidence and scientific interpretation of the evidence. The completeness of the description of unclaimed constituents is not relevant to the determination of patentability. Specific examples of the claimed compounds are, indeed, provided, for example by provision of the formula at page 5, line 14 et seq.

The Examiner has carefully considered this argument but has not found it persuasive.

In Example 5, the compositions of DCP are suggested by a few qualitative experiments on a plurality of composition in an extract and the composition drawn on page 5 is the result of these experiments. With out isolating every component and subjecting it to structural studies, the applicants have no way of knowing what the true structure(s) is/are. Just because certain moieties are liberated in a chemical reaction does not mean that a structure can be determined from an HPLOC chromatograph or a Bradford protein assay.

Thus, as stated before in the previous office action, the factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the

Art Unit: 1654

claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the predictability or unpredictability of the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to specific compounds deduced from chemical analysis of a mixture of compound isolated from Shilajit. Thus, the claims taken together with the specification imply a specific chemical structure from a complex mixture that are purported to have pharmaceutical and nutritional properties.

*(3) The state of the prior art:*

Shilajit and Shilajit extracts are well known in the art and are well known to contain dibenzo-alpha-pyrone, see Ghosal, S, "Shiljit: Its Origin and Vital Significance", Traditional Medicine, Proceedings of an International Seminar, Nov. 7-9, 1992, Hotel Taj Bengal, Calcutta, India-, pp. 308-319.

*(4) The relative skill of those in the art:*

The relative skill of those in the art is high.

*(5) The predictability or unpredictability of the art: (6) The amount of direction or guidance presented and (7) The presence or absence of working examples: (8) The quantity of experimentation necessary:*

Since the defined core structure that is correlated with the pharmaceutical function remains largely unsolved, means for determining both is highly unpredictable. The specification has provided an alleged structure, or best guess, of a generic. For example, Applicants, in Example 5, state "*This observation suggested that shilajit DCPs are replete with relatively low Mw lipoproteins (like chylomicron/lipocalins). However,  $t_R$  1.5 min signal (Fig. 3) suggested that higher Mw proteins, like B-48, might also occur in DCPs. The presence of adherent ligands, particularly DBPs, was also suggested.*" Suggested is a not ground for enablement and the specification does not provide *specific* examples of the claimed compounds.

Considering the state of the art as discussed by the Wands Factor above and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to synthesize and/or extract and test the compounds that might correlated to a generic structure and test them in a trail and error basis to determine which ones were active and what the structure is that is correlated to function. *It is the examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.*

Art Unit: 1654

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, 13, 14, 17, 26, 29, and the new claims of 39, and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rowland US Patent 5,405,613. Rowland discloses compositions of Shilajit or Shilajit extracts in combination with vitamins (Ca, Fe, K, Mg, Zn, Se in the ranges of 1- 500 ppm as 1 mg/L is approximately 1 ppm) as a pharmaceutical or nutritional supplement. The Shilajit composition was formulated for oral administration and also applied to the skin, readable upon a skin care, pharmaceutical and nutritional formulation. Given the use of Shilajit directly, and not the extract, the composition as a pharmaceutical and/or nutritional supplement would contain **ALL** of the alleged compounds instantly claimed in natural product claims 1, 9, 10, 13, 14, 17, 26, 29, and the new claims of 39, and 40. Therefore the composition as claimed is anticipated by '613.

**New Ground of Rejection**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9, 10, 13, 14, 17, 26, 29, 39, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The response filed 1/16/2007 has introduced NEW MATTER into the claims. Newly added/amended claim(s) 1 and 26 recites "consisting" to replace "comprising." The response did not point out where support for newly added/amended claim(s) 1 and 26 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claim(s) 1 and 26 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in newly added claim(s) 1 and 26, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claim(s) 1 and 26 in the specification or

Art Unit: 1654

claims, as-filed, or remove these limitations from the claims in response to this Office Action.

The specification provides examples of extracts that contain more than the composition claims in Claim 1 and 26. The specification has not taught how to combine only those components of claims 1 and 26, in what ratio, or the source of obtaining those individual components. Therefore, the NEW Matter rejection has been made.

### **Conclusion**

No claims are allowed

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..




Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TSH

  
Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600